

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (original) A method of manufacturing a molded microneedle array comprising:

providing a negative mold insert characterized by a negative image of microneedle topography wherein at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1;

transferring the negative mold insert into an injection molding apparatus, wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity;

heating the negative mold cavity to a temperature above the softening temperature of a moldable plastic material;

heating the moldable plastic material to at least the molten temperature of the moldable plastic material in a chamber separate from the negative mold cavity;

injecting the molten plastic material into the heated negative mold cavity,

allowing the molten plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert;

cooling the molten plastic material to a temperature below the softening temperature of the moldable plastic material; and

detaching the molded microneedle array from the negative mold insert.

2. (original) A method of manufacturing a molded microneedle array comprising:

providing a negative mold insert characterized by a negative image of microneedle topography wherein at least one negative image of a microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1;

transferring the negative mold insert into an injection molding apparatus, wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity;

heating the negative mold cavity to a temperature of more than about 10 degrees centigrade above the softening temperature of a moldable plastic material;

heating the moldable plastic material to at least the molten temperature of the moldable plastic material in a chamber separate from the negative mold cavity;
injecting the molten plastic material into the heated negative mold cavity,
allowing the molten plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert;
cooling the molten plastic material to a temperature at least below the softening temperature of the moldable plastic material; and
detaching the molded microneedle array from the negative mold insert.

3. (currently amended) A method according to claim 1, ~~any one of claims 1 or 2~~, wherein the negative mold insert is formed by:

providing a positive mold master member characterized by microneedle topography wherein at least one microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1;

electroforming a negative mold insert around the positive mold master; and
detaching the negative mold insert from the positive mold master member.

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4. (original) A method according to claim 3, wherein the positive mold master member comprises copper.

5. (currently amended) A method according to claim 1, ~~any one of claims 1 to 4~~, wherein the negative mold insert is fabricated by nickel electroforming.

6. (currently amended) A method according to claim 3, ~~any one of claims 3 to 5~~, wherein the microneedle topography of the positive mold master member is prepared by diamond turning.

7. (currently amended) A method according to claim 1, ~~any one of claims 1 to 6~~, wherein the microneedle array comprises a plurality of microneedles each having a flat tip comprising a surface area measured in a plane aligned with the base of about 20 square micrometers or more and 100 square micrometers or less.

8. (currently amended) A method according to claim 1, ~~any one of claims 1 to 7~~, wherein the microneedle array is formed as part of a larger array, wherein at least a portion of the larger array comprises a non-patterned substrate.

9. (original) A method according to claim 8, wherein the non-patterned substrate has an area of more than about 0.10 square inch (0.65 cm²) to less than about 1 square inch (6.5 cm²).

10. (currently amended) A method according to claim 1, ~~any one of claims 1 to 9~~, wherein the microneedle array comprises a plurality of molded microneedles having a height greater than about 90 percent of the corresponding height of the microneedle topography in the negative mold insert.

11. (canceled)

12. (currently amended) A method according to claim 1, ~~any one of claims 1 to 11~~, wherein the moldable plastic material comprises a material selected from the group consisting of polycarbonate, polystyrene, polyethylene, polypropylene, and blends thereof.

13-14. (canceled)

15. (currently amended) A method according to claim 2, ~~claim 14~~, wherein the negative mold cavity is heated to a temperature of more than about 30 degrees centigrade above the softening temperature of the moldable plastic material.

16. (currently amended) A method according to claim 1, ~~any one of claims 1 to 15~~, wherein the microneedle array comprises a plurality of microneedles having a pyramidal shape.

17. (currently amended) A method according to claim 1, ~~any one of claims 1 to 16~~, wherein the molten plastic material is injected into the heated negative mold cavity with a velocity of less than 2.0 in/sec (5.08 cm/sec).

18. (currently amended) A method according to claim 17, ~~any one of claims 1 to 17~~, wherein after injection of the molten material, it is held at a packed pressure of more than about 6000 psi (40.8 Mpa).

19. (original) A method of manufacturing a negative mold insert used for preparing molded microneedle arrays comprising:

providing a positive mold master member characterized by microneedle topography wherein at least one microneedle is characterized by an aspect ratio of between about 2 to 1 and about 5 to 1;

electroforming a negative mold insert around the positive mold master; and
detaching the negative mold insert from the positive mold master member.

20. (original) A method according to claim 19, wherein the positive mold master member comprises copper.

21. (currently amended) A method according to claim 19, ~~any one of claims 19 to 20~~, wherein the negative mold insert is fabricated by nickel electroforming.

22. (Canceled)

23. (currently amended) A method according to claim 19, ~~any one of claims 19 to 22~~, wherein the positive mold master comprises a plurality of microneedles each having a flat tip comprising a surface area measured in a plane aligned with the base of about 20 square micrometers or more and 100 square micrometers or less.

24-25. (Canceled)

26. (currently amended) A method of manufacturing a molded microneedle array comprising:

providing a negative mold insert prepared according to claim 19, ~~any one of claims 19 to 25~~,

transferring the negative mold insert into a molding apparatus, wherein the negative mold insert is exposed and defines a structured surface of a negative mold cavity;

providing a heated plastic material into the negative mold cavity,

allowing the heated plastic material to fill at least about 90 percent of the volume of the negative indentations defined by the negative mold insert;

cooling the plastic material to a temperature at least below the softening temperature of the plastic material; and

detaching the molded microneedle array from the negative mold insert.

27. (original) A method according to claim 26, wherein the molding apparatus is an injection molding apparatus.

28. (currently amended) A method according to claim 26, ~~any one of claims 26 or 27~~, wherein the negative mold cavity is heated to a temperature of more than about 10 degrees centigrade above the softening temperature of the plastic material prior to providing the heated plastic material to the negative mold.

29. (currently amended) A product manufactured according to the process of claim 1, ~~any one of claims 1 to 28~~.

30. (original) A product according to claim 29, wherein the product is a drug delivery device.